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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,134	03/16/2007	Nigel Tooke	068490-079788	9448

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ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,134	TOOKE ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *26-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *1/10/08 & 12/23/05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/23/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1-25) in the reply filed on April, 29, 2009 is acknowledged. The traversal is on the ground(s) that Groups I and II are related to each other, have a clear special technical feature that relates both the groups and the prior art (Grossman) of the European search report do not anticipate the claims. The arguments were found unpersuasive because of the following reasons: (i) the European search Authority established anticipation of the instant claims by Grossman which indicates that the special technical feature is lacking that binds different Groups of invention together as stated in the previous office action. (ii) the arguments regarding the prior art Grossman et al. were found unpersuasive because the limitations (use of unlabelled oligonucleotides and chemiluminescence detection) were not present in the instant broad claims 1-2 and the broad scope of the independent claims do not exclude the scope of labeled tag and real-time detection as taught by Grossman et al. (iii) a search for one Group, not necessarily result in a related art for the other Group, hence the lack of unity is deemed proper.

Status of Application

2. Claims 1-25 are considered for examination in this office action. Claims 26-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group.

Priority

3. This application filed on March 16, 2007 is a 371 of PCT/EP04/07090 filed on 6/30/04, which claims priority to SWEDEN 0301951-0 filed on 6/30/03 and claims benefit of US provisional 60/481,043 filed on 6/30/2003 and claims benefit of 60/481,319 filed on 9/01/03.

Information Disclosure Statement

4. The Information Disclosure Statement filed on December 23, 2005 has been considered and acknowledged.

Informalities

5. The following informalities are noted:

(i) the independent claims 1-6 recite 'method', it should have been 'A method'.

(ii) the dependent claims 6-25 recite 'method according to claim', it should have been 'the method'.

(iii) the step a) of claims 1-5 recite 'a nucleic acid sample', it should have been 'the nucleic acid sample'.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 1, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

B. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-5 recite 'a nucleic acid sample' in step a) of the claims. The meets and bounds of the claims are unclear and indefinite because, it is not clear whether the method refers to the nucleic acid sample as recited in the preamble of the claims or does it refer to a different nucleic acid sample, that is, method step (a) is not correlating back to preamble of the claims. Further step a) of claim 1 recites 'a genetic element'' and it is not clear whether it is referring to a

different genetic element or to the same genetic element recited in the preamble of the claim.

Amendment of the claim with 'the' or 'said' would obviate the rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A. Claim 1, 21, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Grossman et al. (Nucleic Acids Res., Vol. 22, No. 21, pp. 4527-4534, 1994).

Note: As stated in MPEP 2111.02"[A] claim preamble has the import that the claim as a whole suggests for it." Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also Jansen v. Rexall Sundown, Inc., 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003). The 'microbial typing' in the preamble is not given any patentable weight since it does not give life, meaning and vitality to the claim since the method steps do not require microbial typing.

Grossman et al. teach a method of claim 1 for determining the presence of a genetic element (mutation) in a nucleic acid sample comprising

(a) providing a nucleic acid sample comprising a genetic material (see page 4528, col. 2, paragraph under the sub title 'source of DNA sample and DNA extraction');

(b) providing oligonucleotides that are complementary to said nucleic acid (see page 4529, col. 1, paragraph 1, table III, col. 2, line 1-2);

(c & d) annealing at least two oligonucleotides to said nucleic acid and ligating said oligonucleotides to each other using a ligase enzyme (see page 4529, col. 2, paragraph 1);

(e) detecting ligation-by-product to determine whether a ligation reaction has occurred, as a measure of the presence of the genetic element wherein said method steps are performed simultaneously or subsequently (see page 4529, col. 2, paragraph 2-4, page 4531, col. 2, paragraphs 1-3).

With regard to claim 21, Grossman et al. teach that the nucleic acid is amplified prior to step a) (see page 4529, col. 2, paragraph under sub-title multiplex PCR amplification of CFTR exons).

With regard to claim 25, Grossman et al. teach oligonucleotides to a region outside a region to be analyzed used to generate signal by ligation to normalize a signal generated from the region to be analyzed (see page 4529, col. 2, paragraph under sub-title multiplex oligonucleotide ligation assay of CFTR mutations). Accordingly the claims are anticipated.

B. Claim 1-2, 6, 15, 16, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Schalling et al. (US 5,695,933).

Schalling et al. teach a method of claims 1-2, 15, for determining the presence of a genetic element (nucleotide repeat) in a nucleic acid sample comprising

(a) providing a nucleic acid sample comprising a genetic material a genetic element (see col. 1, line 66-67, col. 2, line 1-19);

(b) providing oligonucleotides that are complementary to said nucleic acid (see col. 2, line 1-19);

(c & d) annealing at least two oligonucleotides to said nucleic acid and ligating said oligonucleotides to each other using a ligase enzyme (see col. 2, line 2-34);

(e) detecting ligation-by-product to determine whether a ligation reaction has occurred, as a measure of the presence of the genetic element wherein said method steps are performed simultaneously or subsequently (see col. 2, line 35-46).

With regard to claim 6, 16, 25, Schalling et al. teach that an oligonucleotide in step b) is adapted to anneal immediately outside a repeated sequence and the signal generated from said oligonucleotide is used to normalize the signal generated form a region to be analyzed (see col. 2, line 20-34, col. 6, line 1-10). Accordingly the claims are anticipated.

C. Claim 1-13, 19, 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Jansson et al. (US 2008/0044813A1).

Jansson et al. teach a method of claims 1-5, for determining the presence of a genetic element (mutation or single nucleotide polymorphism) in a nucleic acid sample (bacteria or virus sample) comprising

(a) providing a nucleic acid sample comprising a genetic material a genetic element (see page 1, paragraph 0004);

(b) providing oligonucleotides that are complementary to said nucleic acid (see page 1, paragraph 0007);

(c & d) annealing at least two oligonucleotides to said nucleic acid and ligating said oligonucleotides to each other using a ligase enzyme (see page 1, paragraph 0007);

e (i) converting ligation-by-product to ATP (see page 2, paragraph 0019);

(e) detecting ligation-by-product to determine whether a ligation reaction has occurred, as a measure of the presence of the genetic element wherein said method steps are performed simultaneously or subsequently (see page 1, paragraph 0007, page 2, paragraph 0019).

With regard to claims 6, 16, Jansson et al. teach that an oligonucleotide is adapted to anneal immediately outside a repeated sequence (target sequence) (see page 1, paragraph 0007).

With regard to claim 7, Jansson et al. teach that the ligation-by-product is AMP (see page 1, paragraph 0007).

With regard to claim 8, 10-12, Jansson et al. teach that said step d) is performed employing a NAD+dependent DNA-ligase or ATP dependent ligase using dATP as a substrate (New England bio labs and Amersham Biosciences) (see page 1, paragraphs 0001-0003, paragraph 0014).

With regard to claim 9, Jansson et al. teach that step e) is performed employing a pyruvate phosphate dikinase (see page 2, paragraph 0020, 0029).

With regard to claim 13, Jansson et al. teach that the ligation-by-product is pyrophosphate (PPi) (see page 2, paragraph 0019).

With regard to claim 19, Jansson et al. teach that the nucleic acid sample is immobilized to a support (see page 2, paragraph 0016-0018).

With regard to claim 22, Jansson et al. teach that the luciferase-based assay is a luminometric assay (page 2, paragraph 0019). Accordingly the claims are anticipated.

D. Claim 1-7, 9, 13-14, 16-18, 20, 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shultz et al. (US 6,235,480).

Shultz et al. teach a method of claims 1-5, for determining the presence of a genetic element (repeat sequences or single nucleotide polymorphism) (see col. 56, line 9-22) in a nucleic acid sample (bacteria or virus sample) comprising

(a) providing a nucleic acid sample comprising a genetic material a genetic element (see col. 22, line 3-7);

(b) providing a pair of oligonucleotides that are complementary to said nucleic acid (see col. 22, line 7-22);

(c & d) annealing at least two oligonucleotides to said nucleic acid and ligating said oligonucleotides to each other using a ligase enzyme (see col. 22, line 3-59);

e (i) converting ligation-by-product to ATP (see col. 37, line 22-37);

(e) detecting ligation-by-product to determine whether a ligation reaction has occurred, as a measure of the presence of the genetic element wherein said method steps are performed simultaneously or subsequently (see col. 22, line 3-59).

With regard to claims 6, 16, Shultz et al. teach that an oligonucleotide is adapted to anneal immediately outside a repeated sequence (target sequence) (see col. 22, line 3-22).

With regard to claim 7, Shultz et al. teach that the ligation-by-product is AMP (see col. 41, line 42-56).

With regard to claim 9, Shultz et al. teach that step e) is performed employing a pyruvate phosphate dikinase (see col. 50, line 7-10).

With regard to claim 13, Shultz et al. teach that the ligation-by-product is pyrophosphate (PPi) (see col. 41, line 42-56).

With regard to claim 22, Shultz et al. teach that the luciferase-based assay is a luminometric assay (see col. 41, line 42-47).

With regard to claims 14, 23-24, Shultz et al. teach that the light produced by a luciferase reaction is enzymatically turned off by the addition of apyrase (ATP-sulfurylase) (see col. 50, line 7-17).

With regard to claims 17-18, 20, Shultz et al. teach that the unannealed oligonucleotides are removed by using exonuclease, phosphatase or by washing (see col. 30, line 64-67, col. 31, line 1-2, col. 38, line 15-35, col. 108, line 55-67, col. 109, line 1-21). Accordingly the claims are anticipated.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637